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| APPLICATION NO.                                     | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO.            |
|---|-------------|----------------------|---------------------------------|-----------------------------|
| 10/656,055  | 09/05/2003  | Debbie Yaver         | 10322.200-US                    | 8946                        |
| 25907   | 7590        | 06/25/2009           |                                 |                             |
| NOVOZYMES, INC.<br>1445 DREW AVE<br>DAVIS, CA 95616 |             |                      | EXAMINER<br>HINES, JANA A       |                             |
|   |             |                      | ART UNIT<br>1645                | PAPER NUMBER                |
|   |             |                      | NOTIFICATION DATE<br>06/25/2009 | DELIVERY MODE<br>ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-CA@novozymes.com

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/656,055 | <b>Applicant(s)</b><br>YAYER ET AL. |  |
|                              | <b>Examiner</b><br>JaNa Hines        | <b>Art Unit</b><br>1645             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1, 11, 36, 42, 43, 82-88 and 90-93 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 11, 36, 42, 43, 82-88 and 90-93 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on March 30, 2009 has been entered.

### ***Claim Status***

2. Claims 2-10, 12-35, 37-41, 44-81 and 89 are cancelled. Claims 1, 11, 36, 42-43, 82-88 and 90-93 are under consideration in this office action.

### ***Response to Arguments***

3. Applicant's arguments filed March 30, 2009 have been fully considered but they are not persuasive.

### ***Previous Grounds of Rejection***

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 11, 36, 42-43, 82-88 and 90-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al., (PNAS, 1999. Vol. 96(22): 12833-12838) in view of Cao et al., (Mol. Microbio. 2002. Vol. 45(5): 1267-1276).

The rejection was on the grounds that it would have been *prima facie* obvious at the time of applicants' invention to apply the *Bacillus subtilis* strain used in DNA hybridization microarrays of Cao et al., to Wilson et al., method for determining the mode of action of an antimicrobial compound comprising detecting hybridization complexes and assigning a mode of action in order to provide obtain antimicrobial mode of action results for *B. subtilis* which is known to be resistant to known antimicrobial drugs.

### ***Response to Arguments***

5. Applicant's arguments filed March 30, 2009 have been fully considered but they are not persuasive.

Applicants submit that Wilson et al., and/or Cao et al., do not teach or suggest the instant invention. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it

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would have been prima facie obvious to combine the invention of Wilson et al., and Cao et al., to advantageously achieve a determining drug-induced alterations in gene expression by microarray hybridization for multi-drug resistant bacteria.

Applicants point to Wilson et al., teaching of 0.2 µg/ml or 1 µg/ml for isoniazid (INH) and assert that Wilson et al., amounts are above the minimum inhibitory concentrations; therefore Wilson et al, amount is not a subinhibitory amount. However it is noted that the specification does not define subinhibitory amount to be above or below the minimum inhibitory concentration of INH. It is noted that no particular formulation is disclosed by the specification or recited by the claims to determine the subinhibitory amount. "The ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313<, 75 USPQ2d 1321>, 1326 (Fed. Cir. 2005) (en banc). *Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003); *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 67 USPQ2d 1132, 1136 (Fed. Cir. 2003)("In the absence of an express intent to impart a novel meaning to the claim terms, the words are presumed to take on the ordinary and customary meanings attributed to them by those of ordinary skill in the art."). It is the use of the words in the context of the written description and customarily by those skilled in the relevant art that accurately reflects both the "ordinary" and the "customary" meaning of the terms in the claims. *Ferguson Beauregard /Logic Controls v. Mega Systems*, 350 F.3d 1327, 1338, 69 USPQ2d 1001, 1009 (Fed. Cir. 2003).

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Thus it would appear that subinhibitory means an amount that is not able to kill the bacteria, and can modify their physico-chemical characteristics and the architecture of their outermost surface and may interfere with some bacterial functions. The 0.2 µg/ml or 1 µg/ml for INH taught by Wilson et al., clearly does not kill the bacteria, and meets the limitation of a subinhibitory amount, since Wilson et al., teach exploring drug-induced alterations in gene expression by microarray hybridization.

Furthermore, Schaaf et al., (Eur J. Clin. Microbiol. Infect. Dis. 2006. Vol. 26:203-205) teach the minimal inhibitory concentration (MIC) of isoniazid (INH) of low level INH-resistant organisms is 0.2 - 5 µg/ml. Therefore the 0.2 µg/ml is far lower than the MIC amount of 5µg/ml. Therefore in the alternative, even if the "subinhibitory amount" were defined by the MIC number, Wilson et al., teach a subinhibitory amount and applicants arguments and statements are not found persuasive.

Applicants argue that the instant facts are different and that Applicants have not optimized the minimum inhibitory range of an antimicrobial compound but used subinhibitory concentrations. However it is still the Office's position that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this case, the prior art sets forth the use of subinhibitory amounts when detecting hybridization complexes; therefore Applicants use of a workable range of subinhibitory amounts is not found persuasive to overcome the prior art rejection. See also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known

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provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.”).

Applicants argue that Wilson et al., in view of Cao et al., teach away from using subinhibitory amounts of an antimicrobial compound. However it is the examiner's position that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). However, “the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed....” *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). It is the position of the Office that that applicant's argument that the reference teaches away from using subinhibitory amounts was insufficient to overcome the rejection since Applicants have not asserted discovery beyond what was known in the art. Wilson et al., clearly and specifically teach the growth and drug treatment of the strain wherein cultures grown and treated with 0.2µg/ml or 1µg/ml the antimicrobial compound which meet the limitations of subinhibitory amounts contrary to Applicants assertions. Therefore contrary to applicants' argument, the prior art does not teach away from the instant claims.

Applicants submit that the claimed method have produced unexpected results in utilizing subinhibitory amounts. Objective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value includes evidence of unexpected results. Applicants have not presented any experimental data showing that

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prior detecting hybridization and assigning a mode of action for the antimicrobial compound obtained by culturing cells in the presence of at least one subinhibitory amount of an antimicrobial compound produced unexpected results. Due to the absence of evidence, it must be concluded that applicants' assertions of unexpected results constitute mere argument. It is noted that merely supplying the resultant action of using subinhibitory amounts does not constitute unexpected results. Attorney statements are not evidence and must be supported by an appropriate affidavit or declaration that includes statements regarding unexpected results. Thus it appears that the use of sub-inhibitory amount is not unexpected.

Therefore Applicants' argument is not persuasive and the rejection is maintained.

### ***Conclusion***

6. No claims allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Robert Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/  
Examiner, Art Unit 1645

/Mark Navarro/  
Primary Examiner, Art Unit 1645